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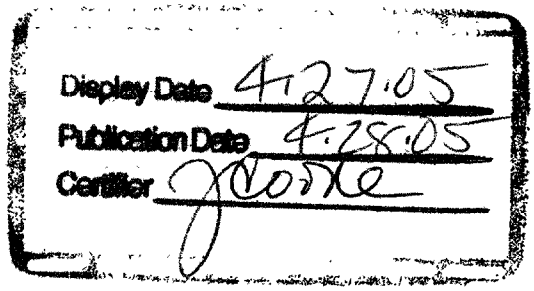
DEPARTMENT OF HEALTH AND HUMAN SERVICES



Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Penicillin G Benzathine and Penicillin G Procaine Sterile Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Cross Vetpharm Group Ltd. The supplemental NADA provides for the addition of statements to labeling of an injectable penicillin suspension warning against the use of this product in calves to be processed for veal. FDA is also amending the regulations to correctly identify approved indications for use for several penicillin products. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.gov.*

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed a supplement to NADA 65–506 that provides for the addition of statements to labeling of COMBI–PEN–48 (penicillin G benzathine and penicillin G procaine) injectable suspension warning against the use of this product in calves to be processed for veal. The supplemental

2005-065-506

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NADA is approved as of March 23, 2005, and the regulations are amended in § 522.1696a (21 CFR 522.1696a) to reflect the approval. FDA is also amending § 522.1696a to correct an error in the indications for use for several penicillin products which was introduced during reformatting of this section in 2001 (66 FR 711, January 4, 2001). This is being done to improve the accuracy of the regulations.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 522.1696a is amended by revising the section heading and paragraphs (b)(2), (b)(3), and (d)(2)(iii) to read as follows:

§ 522.1696a Penicillin G benzathine and penicillin G procaine suspension.

* * * * *

(b) * * *

(2) Nos. 010515, 059130, and 061623 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(2)(iii) of this section.

(3) Nos. 000856 and 049185 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(B), and (d)(2)(iii) of this section.

* * * * *

(d) * * *

(2) * * *

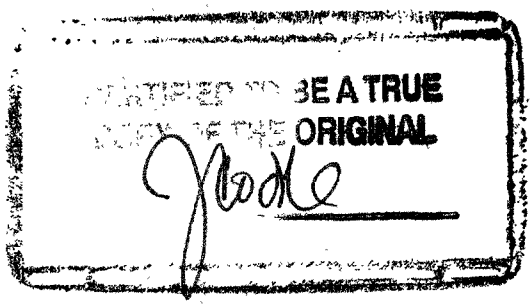
(iii) *Limitations.* Limit treatment to two doses. Not for use within 30 days of slaughter. For Nos. 010515, 049185, 059130, and 061623: A withdrawal

period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

Dated: April 8, 2005
April 8, 2005.

Steven D. Vaughn DVM

Steven D. Vaughn,
Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.



[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

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